

Norrköping Randomised Controlled Trial of Prostate Cancer Screening

Submission date 26/04/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/06/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 26/05/2011	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
92044 (Linköping, Sweden, 1987)

Study information

Scientific Title

Prostate screening for men aged 50-69 in Norrköping, Sweden: A twelve-year randomised controlled trial with twenty-year follow up

Study objectives

Screening for prostate cancer is cost effective, well accepted and reduces prostate cancer mortality

Ethics approval required

Old ethics approval format

Ethics approval(s)

Research Ethics Committee, Faculty of Health Sciences in Linköping (forskningsetikommittén, Hälsouniversitetet i Linköping) approved on the 8th of April 1992 (ref: 92044)

Study design

Randomised Controlled Trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Screening

Participant information sheet

Please contact Gabriel Sandblom [gabriel.sandblom@ki.se] to request a patient information sheet

Health condition(s) or problem(s) studied

Prostate Cancer

Interventions

1494 men were randomly selected from a population of 9026 men aged 50-69 (the total male population of that age in the area).

Information was issued through local media and an invitation to screening sent to selected individuals.

Screening was conducted every third year from 1987-1996. Digital rectal examination only was performed in 1987 and 1990. PSA testing (cut-off level 4 ng/ml) was added in 1993 and 1996.

The total duration of follow up was 15-20 years.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Prostate Cancer mortality, determined by obtaining data from the Swedish Central Death Register on date and cause of death. Cause of death was also checked in the South-East Region Prostate Cancer Register.

Secondary outcome measures

1. Cost effectiveness, determined when twelve year survival data were accessible
2. Acceptance, assessed by questionnaires immediately after the screening examinations
3. Diagnostic accuracy

Further information on the outcomes and methods of assessment may be found in the publications below.

Overall study start date

01/01/1987

Completion date

31/12/2010

Eligibility

Key inclusion criteria

Men aged 50-69 years in 1987 residing in Norrköping, Sweden.

Participant type(s)

Patient

Age group

Adult

Sex

Male

Target number of participants

9000

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/01/1987

Date of final enrolment

31/12/2010

Locations

Countries of recruitment

Sweden

Study participating centre

Department of Urology

Linköping

Sweden

581 91

Sponsor information

Organisation

Research Council of Southeast Sweden (Forskningsrådet i Sydöstra Sverige) (Sweden)

Sponsor details

Forskningsrådet i Sydöstra Sverige

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Sponsor type

Research council

ROR

<https://ror.org/0326gsy75>

Funder(s)

Funder type

Research council

Funder Name

The Research Council in the SouthEast Region of Sweden (Sweden) - (number F97-318)

Funder Name

The Swedish Cancer Foundation (Sweden)

Funder Name

County Council of Östergötland (Sweden)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	21/04/1990		Yes	No
Results article	results on cost effectiveness	01/12/1990		Yes	No
Results article	results	01/12/1992		Yes	No
Results article	results	01/08/1993		Yes	No
Results article	results	01/12/2004		Yes	No
Results article	20 year follow up results	31/03/2011		Yes	No